

**INTERNATIONAL HEALTHCARE WORKER SAFETY CENTER
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What is a safety-engineered sharp medical device?

U.S. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

In the 2001 revised Bloodborne Pathogens Standard (BPS), OSHA defined “sharps with engineered sharps injury protections” as:

“A nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism *that effectively reduces the risk of an exposure incident*” (OSHA Bloodborne pathogens standard 1910.1030[b]). On line at:

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

The compliance directive for the BPS (CPL 2-2.69 - Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens) offered this further explanation:

“This term encompasses a broad array of devices that make injury involving a contaminated sharp less likely. They include, but are not limited to: syringes with guards or sliding sheaths that shield the attached needle after use; needles that retract into a syringe after use; shielded or retracting catheters used to access the bloodstream for intravenous administration of medication or fluids; intravenous medication delivery systems that administer medication or fluids through a catheter port or connector site using a needle that is housed in a protective covering, blunt suture needles; and plastic (instead of glass) capillary tubes.”

U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The CDC’s “Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program” categorizes and describes different types of safety sharp devices in Appendix B (“Devices with Engineered Sharps Injury Prevention Features”). It also discusses the concept of “active” and “passive” safety devices.

On-line at: <http://www.cdc.gov/Sharpsafety/appendixB.html>

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

The FDA’s design criteria for a safety-engineered sharp medical device can be found in “Guidance for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features” (August 9, 2005), section 5, “Device Design,” p. 6. On-line at: <http://www.fda.gov/cdrh/ode/guidance/934.pdf>

Table 1 from this document (“Design Recommendations for Sharps Injury Prevention Features”) is reproduced below.

Other relevant definitions

“Needleless system”: “A device that does not use needles for: (1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) The administration of medication or fluids; or (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.” (1910.1030[b])

The compliance directive for the BPS (CPL 2-2.69) further explains:

"Needleless systems" provide an alternative to needles for the specified procedures, thereby reducing the risk of percutaneous injury involving contaminated sharps. Examples of needleless systems include, but are not limited to, intravenous medication delivery systems that administer medication or fluids through a catheter port or connector site using a blunt cannula or other non-needle connection, and jet injection systems that deliver subcutaneous or intramuscular injections of liquid medication through the skin without use of a needle."

“Engineering controls”: OSHA explained the meaning of engineering controls in the context of preventing occupational exposures to bloodborne pathogens in the BPS compliance directive:

“Engineering controls’ means controls that isolate or remove the bloodborne pathogens hazard from the workplace. Examples include safer medical devices, such as sharps with engineered sharp injury protection (SESIPs) and needleless systems. These two terms were further defined in the revision to 1910.1030 mandated by the Needlestick Safety and Prevention Act.”

Guidance for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features (August 9, 2005), p. 6.

Table 1. Design Recommendations for Sharps Injury Prevention Features

Type of Feature	Recommendation
All	The user should be able to easily tell whether the sharps injury prevention feature is activated.
All	Once activated, the sharps injury prevention feature cannot be deactivated and should remain protective through disposal.
Active (i.e., feature requires activation by the user)	It should be possible to activate the feature with a single-handed technique, allowing the user’s hands to remain behind the exposed sharp.
Needle Shield	The shield should completely enclose the needle and prevent finger access when activated.
Retractable Sharp	The sharp should be fully retracted within the housing of the device.
Fixed Recessed Needle	The housing should extend beyond, i.e., fully cover the sharp and prevent finger access.
Colored Feature or Component	The use of color should achieve a specific purpose, (e.g., differentiate device models or sizes) and conform with user conventions, (e.g., orange hubs and needle covers for insulin syringes).